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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/809,600	03/24/2004	David Nordman	L-8XCI	7238
23557 7590 02/23/2010 SALIWANCHIK LLOYD & SALIWANCHIK A PROFESSIONAL ASSOCIATION PO Box 142950 GAINESVILLE, FL 32614				
EXAMINER GRUN, JAMES LESLIE				
ART UNIT		PAPER NUMBER		
1641				
NOTIFICATION DATE		DELIVERY MODE		
02/23/2010		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

euspto@slspatents.com

Office Action Summary**Application No.**

10/809,600

Applicant(s)

NORDMAN ET AL.

Examiner

JAMES L. GRUN

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 February 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27, 30 and 32-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 27, 30 and 32-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12 February 2010 has been entered.

The new claims filed 12 February 2010 as claims 31-33 were renumbered under 37 CFR § 1.126 as claims 32-34, respectively. Claims 1-26, 28, 29, and 31 have been cancelled. Claims 27, 30, and 32-34 remain in the case.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 27, 30, and 32-34 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 27 and claims dependent thereupon, it is not clear what is encompassed by a "blood, tissue, or urine serum sample" as is now claimed. In these claims, the terms "homologous and/or orthologous" are vague. The terms have the inference of common evolutionary origin and/or divergence due to speciation. It is not clear as to what applicant intends as within the metes and bounds of the invention and what applicant intends as excluded therefrom because the terms are vague and indefinite in the absence of a clear description or definition of what the terms mean. Without a clear and unambiguous description of what is

intended, which is found neither in the specification nor the claims, the metes and bounds cannot be determined.

Applicant's arguments filed 12 February 2010 have been fully considered but they are not deemed to be persuasive. Notwithstanding applicant's assertions to the contrary, the terms "homologous and/or orthologous" can have different meanings and would not be well-understood or readily recognized as to what applicant intends as encompassed without a clear description or definition of what the terms mean in the context of the invention. The exemplification of a single genus, HLA antigens, is not found to provide a clear description or definition of what the terms mean in the context of the invention. Notwithstanding applicant's assertions to the contrary, applicant's amendments have not obviated rejections under this statute for the reasons set forth above.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 27 and 30 are rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Hoffman et al. (US 5,599,543) for reasons of record.

Claims 27 and 30 are rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Geysen et al. (Proc. Natl. Acad. Sci. USA 81: 3998, 1984) for reasons of record.

Applicant's arguments filed 12 February 2010 have been fully considered but they are not deemed to be persuasive.

Notwithstanding applicant's assertions to the contrary, "peptide circumsporozoite protein repeat regions of different parasite **species**" (emphasis added) in the reference of Hoffman et al. are clearly homologous and/or orthologous antigens, were used as negative antigen controls with each tested serum sample (see e.g. col. 7), and clearly anticipate the invention as instantly claimed when taken with the teachings therein as noted in the reasons of record, e.g. **"values from the negative control wells** as well [as] those of the negative control sera **are subtracted from the relevant antigen wells** for determinations of positive responses" (emphasis added). Notwithstanding applicant's assertions to the contrary, the additional use of a monoclonal antibody reacting with a negative control antigen as an additional positive control as taught in the reference is unrelated to the use of the antigen as a negative control with patient serum samples and does not indicate that the antigen was not used as a negative control subtracted from the value obtained with each serum sample as taught in the reference.

Applicant again urges that Geysen et al. do not teach identifying the least reactive capture reagent for use as a negative control. This is again not found persuasive for the reasons of record. The reference teaches positives in those wells with values above value(s) in the well(s) chosen as the negative, which, if not a case in which all or none of the peptides react, can be the value(s) for the peptide(s) having the generally uniform background level. The reference clearly exemplifies an assay in which only a single capture peptide does not react and would be selected as the negative control (see e.g. Fig. 3 and Table 1, W substitution for D at position 2 (residue 147) of the peptide reacted with serum 48) based on the disclosure.

Notwithstanding applicant's assertions to the contrary, the references are found to clearly anticipate the invention as instantly claimed and the rejections are herein maintained for the reasons of record and as set forth above.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James L. Grun, Ph.D., whose telephone number is (571) 272-0821. The examiner can normally be reached on weekdays from 9 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya, SPE, can be contacted at (571) 272-0806.

The phone number for official facsimile transmitted communications to TC 1600, Group 1640, is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application, or requests to supply missing elements from Office communications, should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/J. L. G./
James L. Grun, Ph.D.
Examiner, Art Unit 1641
February 21, 2010

/Shafiqul Haq/
Primary Examiner, Art Unit 1641